CENTERS FOR MIND/BODY INTERACTIONS AND HEALTH

Release Date: January 22, 1999

RFA: OD-99-005

P.T.

Office of Behavioral and Social Sciences Research
National Cancer Institute
National Heart, Lung, and Blood Institute
National Institute on Aging
National Institute on Alcohol Abuse and Alcoholism
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Child Health and Human Development
National Institute of Dental and Craniofacial Research
National Institute on Drug Abuse
National Institute of General Medical Sciences
National Institute of Mental Health
National Institute of Neurological Disorders and Stroke
National Institute of Nursing Research

Letter of Intent Receipt Date: March 1, 1999
Application Receipt Date: April 23, 1999

PURPOSE

The Office of Behavioral and Social Sciences Research (OBSSR), National Cancer Institute (NCI), National Heart, Lung, and Blood Institute (NHLBI), National Institute on Aging (NIA), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institute of Child Health and Human Development (NICHD), National Institute on Drug Abuse (NIDA), National Institute of Dental and Craniofacial Research (NIDCR), National Institute of General Medical Sciences (NIGMS), National Institute of Mental Health (NIMH), National Institute of Neurological Disorders and Stroke (NINDS), and the National Institute of Nursing Research (NINR) invite applications for Specialized Center Grants (P50) grants in order to encourage behavioral, psychological, social, and

biomedical research on the interrelationships among cognition, emotion, biological processes, and physical health. The NIH sponsoring organizations are issuing this Request for Applications (RFA) to foster interdisciplinary research on the interactions among the mind and body in health and disease. Applications in response to this RFA are encouraged to propose research topics ranging from basic research to those involving clinical applications.

HEALTHY PEOPLE 2000

Each NIH RFA addresses one or more of 22 Health Promotion and Disease Prevention priority areas. These areas can be found via the WWW at http://www.crisny.org/health/us/health7.html

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Foreign organizations are not eligible. However, foreign organizations may participate if they are components of domestic, U.S. organizations or via contractual or consortium agreements with domestic, U.S. organizations. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators. Questions about eligibility may be addressed to the program contacts listed under INQUIRIES.

To be considered, applicant organizations must have a Principal Investigator (PI) who is a recognized leader in the proposed field of research with a demonstrated history of research funding and scientific productivity as well as demonstrated experience in the administration of complex research projects such as multiple, simultaneous research project grants (R01s), program project grants (P01), center grants, or multi-site clinical investigations. The PI should have demonstrated ability to oversee and conduct planning activities, provide direction to the Center, ensure an interdisciplinary research emphasis, and build a career development program.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) specialized center grant (P50) mechanism. This mechanism supports the full range of research and development from basic to clinical and intervention studies, as well as health services, policy, and surveillance research. These grants differ from traditional program project grants in that they are more complex and flexible in terms of the activities that can be supported. In addition to support for interdisciplinary

research projects, support may be provided for career development research activities, a limited number of pilot research projects, and specialized resources and shared facilities aimed at supporting the range of proposed research. PIs will be responsible for the planning, direction, and execution of the proposed program. Awards will be administered under NIH grants policy as stated in the most recent NIH Grants Policy Statement.

P50 awards provide support for a broad interdisciplinary research program consisting of related research endeavors and associated core infrastructure to ensure their effective and synergistic functioning. The activities included in the supported research must be thematically integrated, interdisciplinary, and synergistic. Research supported through this mechanism must reflect in clear ways interdependence of components of the research program that would not occur simply from the mere collection of the individual components. Taken as a whole, a center is expected to enable a level of achievement that exceeds that expected on the basis of the "sum of its parts." Further, each center is encouraged to address the range of research, from basic to clinical applications, around the central theme of the center. Center support should be essential to the achievement of the work that is proposed. They are expected to attract established and promising investigators into Mind/Body Research and to provide opportunities for research experience, career development, and mentoring.

FUNDS AVAILABLE

The estimated funds available for the first year of support for a maximum of five centers awarded under this RFA are $10,000,000. Applicants may request up to $2,000,000 in annual total costs (direct and indirect costs combined). Annual increases are limited to three percent. The total project period for an application may not exceed five years. The anticipated award date for all applications is September 30, 1999.

Funding in response to this RFA is dependent upon the receipt of a sufficient number of applications of high scientific merit and upon the anticipated availability of funds for this purpose. Depending on NIH priorities and budget at the end of the five-year award period, a RFA may be issued to continue the Centers Program. If the RFA is not reissued, then grantees will have to compete for support through other research grant mechanisms (e.g., R01, P01).

RESEARCH OBJECTIVES

(1) Background

The Public Health Service has documented that many of the leading causes of morbidity and mortality in the U.S. are attributable to social, behavioral, and lifestyle factors (e.g., tobacco use, lack of exercise, poor diet, and alcohol abuse). Numerous studies have also documented that psychological stress is linked to a variety of health outcomes, and researchers and public health officials are becoming increasingly interested in understanding the nature of this relationship. Research has shown, for example, that psychological stress can contribute to increased heart disease and decreased immune system functioning. Other research has demonstrated that cognition (attitudes, beliefs values), social support, prayer, and meditation can reduce psychological stress and contribute to positive health outcomes. Consequently, over the past decade the National Institutes of Health have increased efforts to encourage and support Health and Behavior Research (e.g., RFA on Innovative Approaches to Disease Prevention Through Behavior Change, NIH Guide to Grants and Contracts, Volume 26, Number 36, October 24, 1997). Mind/Body Research is viewed as one component of Health and Behavior Research. The purpose of this RFA is to build upon and expand the scientific foundation in this area in order ultimately to develop and implement effective interventions to improve health and functioning.

For the purposes of this RFA, Mind/Body Research encompasses behavioral, social, and biomedical research on the interrelationships among stress, cognition, emotion, biological processes, and physical health. Research activities supported under this RFA should go beyond merely documenting the relationship between stress and illness; it should elucidate the mind/body pathways or processes linking them.

(2) Areas of Emphasis

Three areas of research are emphasized. In addition, special importance is given to Mind/Body Research in diverse racial/ethnic and socioeconomic status populations (e.g., cultural beliefs regarding health; perceived racism and health; distrust of health care systems and health care utilization). The formation of multidisciplinary teams to perform the research of this initiative is viewed as essential.

o The first area of emphasis is the effects of beliefs, attitudes, and values on physical health, including research on social, psychological, behavioral, affective, and biological factors mediating these effects.

o The second emphasis is on determinants or antecedents of health-related beliefs, attitudes, or values. That is, given that some beliefs and attitudes have been shown to affect health, how are these beliefs, attitudes, and values developed, maintained, or changed?

Specifically, this RFA will support research addressing issues such as: What are the physiological, behavioral, or social pathways by which beliefs, attitudes, and values or particular stress-management interventions affect health? What are the physiological and/or behavioral underpinnings of placebo effects? What contributes to individual differences in the beliefs, attitudes, and values that affect health and biological processes? How are health-related beliefs, attitudes, and values formed, maintained, and changed? What are the factors that lead to individual differences in how stress is experienced and in the health consequences of stress? How do social class, family, culture, disability, age, gender, or ethnicity influence health-related beliefs, attitudes, and values?

o The third is on how stress influences physical health, including: (a) basic research investigating how attitudes, beliefs, and values influence perceived stress, individual differences in the biology of stress, and interactions between stress and behavioral risk factors for disease; (b) behavioral and biological mediators of the relationship between stress and health or disease, and (c) the evaluation of relaxation response-based interventions or other stress management interventions for physical illness and/or biological functioning. Relaxation response-based interventions are those that result in reduced physiological arousal. They include such stress management approaches as meditation, autogenic relaxation, progressive muscle relaxation, breathing exercises, or the focused repetition of a word, sound, prayer, or phrase. These interventions may be examined alone or in conjunction with other stress management techniques such as cognitive therapy and support groups. Research proposals examining aspects of successful stress-management interventions, including relaxation response-based interventions or the interaction of these interventions with other stress management approaches, are also invited.

Issues such as the following would be appropriate here: Through which psychological or physiological pathways do relaxation response-based interventions or other stress management approaches affect health? What are the effective components in successful stress-management practices? Does the combination of relaxation response-based approaches with other stress management techniques improve outcome? Are particular stress-management interventions more effective for certain individuals, populations, or health outcomes? Can successful stress-management practices be effectively implemented in natural settings? What are the possible economic implications of utilizing stress management interventions?

Twelve NIH Institutes have joined with OBSSR to support this initiative. Examples of topics of interest to specific Institutes are:

The NATIONAL CANCER INSTITUTE is particularly interested in stimulating research with cancer patients and survivors that examines interactions among psychological factors, immune, neuroendocrine, genetic, and other potential biological mediators, and disease related outcomes. These outcomes might include disease free survival, number, type and severity of disease recurrence, incident co- morbidities diagnosed during treatment and/or follow-up and health related quality of life. Special emphasis is placed on research that examines mind/body mechanisms through the development of novel methods and integrative conceptual models. In addition, the impact of psychological and behavioral interventions on outcomes such as adaptation or adherence to treatment regimens, post-treatment follow-up recommendations, and screening behaviors relevant to secondary and tertiary prevention in cancer survivors is of interest.

The NATIONAL HEART, LUNG, AND BLOOD INSTITUTE is interested in the study of relationships between mental states and any of the diseases or conditions under its mandate. Included is research on the role of stress in coronary heart disease and hypertension, the experience of pain due to a disease or condition, causes or precipitants of asthma, and sleep disorders. Applications should describe an integrated, interdisciplinary research program that includes the following: a) basic research to identify the biological mechanisms that underlie associations between mental states (such as stress) and disease, conducted in animal models or humans; b) clinical research to investigate the role of stress or related mental attributes on conditions such as atherosclerosis, asthma, or acute cardiac events; and, c) testing of clinically beneficial interventions such as stress management techniques, cognitive behavior therapy, or other approaches to improve adherence to therapy, effectiveness of medical treatment, or prevention of disease in the general population or in targeted groups. Applicants are encouraged to consider research approaches that develop or apply promising new technologies, such as ambulatory techniques for real-time assessment of behavioral and psychological states, event-related functional magnetic resonance imaging (fMRI), or genetic technologies that may improve understanding of relationships between mental states and disease. Other research that may be of interest to this solicitation is described in the Report of the NHLBI Task Force on Behavioral Research in Cardiovascular, Lung, and Blood Health and Disease, available at http://www.nhlbi.nih.gov/nhlbi/sciinf/taskforc.htm

The NATIONAL INSTITUTE ON AGING solicits research on how aging-related processes influence Mind/Body interactions. NIA is interested in integrative studies that consider the impact

of beliefs and experiences across multiple systems and pathways (e.g., influences on cardiovascular, neuroendocrine, or immunological systems) of relevance to the health of older people. In addition to single disease or organ approaches, NIA focuses on mind/body interactions that influence overall psychosocial and physiological functioning in later life as well as the onset and course of an array of age-related illnesses and conditions including arthritis, cancer, cardiovascular and cerebral functioning, dementia, diabetes, hypertension, stroke, etc. Examples of particular topics of interest include: how individual factors, the social context (e.g., sociodemographic factors, social institutions, social density, crime rates, responsiveness to changing physical challenges) influence and maintain health-related attitudes and behaviors in old age; the psychosocial and physiological pathways (e.g., molecular, cellular, and integrative neural systems) linking beliefs and value systems with health and functional outcomes for older people as they age; and the design, testing and comparison of stress-management interventions for improving the health and functioning of older people. Special emphasis is placed on the most socially (e.g, low SES or minority status) and/or clinically vulnerable older population where the links among stress, biological processes, and health may be especially potent, and where beliefs can play a major role in the definition of and reaction to stressors. A cohort and life-course perspective is important in understanding factors that influence the development and modification of specific health beliefs and attitudes (e.g., impact of stressful life transitions such as widowhood, retirement, or geographic relocation). Also important is an understanding of how old age affects the design and evaluation of proposed interventions.

The NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM encourages applications addressing spirituality as a mediator for Twelve Step Facilitation and effectiveness in treatment for alcohol-related problems; effects of attitudes, beliefs, and expectancies on responses to acute administration of alcohol, initiation of alcohol- seeking behavior, development of addictive behavior, inability to stop drinking, treatment efficacy and effectiveness; ability of relaxation training and increased self-efficacy to enhance effectiveness of cognitive behavioral therapy for alcohol-related problems; and behavioral and social techniques for increasing compliance with alcohol treatment and prevention efforts.

The NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES is particularly interested in the use of cognitive behavior therapy for pain management in rheumatic diseases such as fibromyalgia and in low back pain, the adaptation of self-efficacy programs in management of chronic diseases such as arthritis and osteoarthritis to minority populations, and the association between potentially modifiable psychosocial factors and disease activity and health status in immunological disorders such as lupus.

The NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT is particularly interested in interdisciplinary research projects examining the role of health- related beliefs or attitudes on achieving and maintaining health and well-being of children and youth with physical, learning or developmental disabilities. These studies could include, but are not limited to, studies on the antecedents and consequences of health-related beliefs or attitudes, studies on gender and stress response in persons with disabilities, or interventions that promote specific outcomes in particular populations of children.

The NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH is particularly interested in supporting research that exploits the accessibility of the oral cavity in studying mechanisms underlying mind/body interrelationships. For example, the use of saliva or other oral tissues as diagnostic for stress and stress-related physiological states would be of interest. In addition, disease processes occurring in the oral cavity are related to and/or influenced by disease in other, more remote, parts of the body (e.g., cardiovascular, respiratory diseases, diabetes). Mental states (e.g., depression, stress) may influence both oral cavity and other diseases as well as be the intervening condition connecting them. The utilization of common dental interventions (e.g., tooth extractions, gum surgery) or common infectious or chronic oral/craniofacial diseases and conditions (periodontal diseases, TMJ/masticatory muscle disorders, salivary disorders) could potentially provide powerful and practical models for testing the mechanisms underlying mind/body associations and evaluating the biological outcomes of stress-management interventions. Of particular relevance is research on the relationships between beliefs, attitudes, and/or values and (a) the speed of oral mucosal wound healing following oral surgeries (third molar extraction, periodontal surgery), (b) oral mucosal barriers to infection (i.e., immunological defense), (c) responses to pain in the oral and craniofacial structures, and (d) inadequate or excessive utilization of health care services. Also of interest is research on the biological mechanisms underlying associations between beliefs/attitudes and oral mucosal wound healing, on the mechanisms through which attitudes and behaviors influence risks for developing persisting or chronic craniofacial pain or pain-related disability, and on the effectiveness of stress-management interventions in improving outcomes for persisting craniofacial pain conditions or inherited or chronic disorders (e.g., inherited craniofacial deformities, Sjogren's Syndrome).

The NATIONAL INSTITUTE ON DRUG ABUSE notes that some case studies suggest that hypnosis, relaxation and guided imagery may be effective in treating drug addiction or, in the case of pain patients, may allow for dose reductions of opiates for analgesia. Further controlled research is invited in this area. Also of interest is the use of placebos studied as a possible adjunct to more traditional therapy, both pharmacological and behavioral. In addition, research

that seeks to understanding the underlying neuropsychological mechanisms of placebo in treating drug abuse and relapse is of particular interest. In addition, applications that examine stress as independent and dependent variables, and as a modulating variable in the study of addiction, are sought. For example, proposals that seek to show how stress can lead to drug use and relapse to drug use; the conditions under which drugs are abused to alleviate stress; and whether potential drug abusers are more sensitive to stress are invited. Behavioral, neurobiological/neuroendocrine, and genetic studies will be important in this area, including animal models research. In addition, studies of stress reduction as treatment for drug addiction are sought. Also of interest are studies of how beliefs, attitudes, and expectations about the effects of drugs can induce vulnerability or resilience to using drugs, and how such beliefs can alter the course of addiction treatment. Drug beliefs examined may be either positive (e.g., euphoria, social effects, withdrawal relief, pain control, weight control, antianxiety, attaining spiritual states) or negative (e.g., overdose bad effects, nausea, loss of control, paranoia, aggression), or both. Approaches can include, for example, laboratory studies, linguistic and metaphor analysis, life span studies (e.,g., how these beliefs change with life roles and age), how such beliefs and attitudes change with initiation into drug use and dependence, or during abstinence. Cultural, gender and ethnic differences, as well as the interactive effects of co-morbid states such as AIDS dementia and other mental disorders also are important to examine in this context. Studies of self-esteem, self-worth and self-efficacy, including research into attributions of responsibility for drug addiction and dependence, or attributions about treatment outcomes are relevant.

The NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES is interested in research proposals that address mind/body interactions related to the host's response to and recovery from injury or critical illness, including blunt or penetrating trauma, burn injury, shock, sepsis, surgical procedures, and multiple organ failure. Specific areas of interest include injury or critical illness-induced alterations in localized microcirculation, the inflammatory and immune responses, metabolism and nutritional requirements, and the complex dynamic interactions between tissues or organ systems. NIGMS is also interested in the processes of tissue repair and wound healing following injury. Proposals should focus upon mechanisms at the molecular, cellular, organ, or integrated systemic physiological levels through which mind/body interactions exert any effects.

The NATIONAL INSTITUTE OF MENTAL HEALTH is primarily interested in research that examines fundamental social, psychological, and neurobiological mechanisms involved in health-related beliefs and behaviors, interventions, and physiological states or processes related to health and disease. Priority is placed on understanding processes that promote health or "wellness" and on investigating mechanisms that are fundamental to a range of disorders,

although particular studies may examine these mechanisms in relation to specific disorders or risk factors. Illustrative topics include: Effects of personality variation (e.g., self-efficacy, self-monitoring ability, optimism, neuroticism) on perceptions of risk, symptom reporting, health-related behavior, help-seeking, and adherence to treatment; effects of social relationships and cultural/religious beliefs on health-related attitudes and behaviors; social-psychophysiological mechanisms underlying the effects on health of emotional expression and/or emotion regulation; social, psychological, and neurobiological factors underlying stress responsivity, relaxation, and placebo effects; the social-psychophysiological pathways accounting for effects of socioeconomic status and of social support on health; mechanisms accounting for the influence of mental disorder (e.g., depression) on the incidence or progression of physical disease; and the central, neuroendocrine, autonomic and somatic changes resulting from preventive or therapeutic interventions such as stress-management, meditation, cognitive therapy, and support groups, including the relations of these changes to health outcomes in physical and/or mental disorders. Experimental approaches should encompass the range of cutting-edge methods in social and behavioral science as well as neuroscience (e.g., neuroimaging).

The NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE seeks research on the interrelationships between psychological state, e.g., motivation, attitude, mood and emotion on neurological disorders, with particular emphasis on the following four topics. (1) Pain: Even though their basic physiology may be similar, people react in very different ways to pain, perhaps due to stress, psychological state, gender, and cultural background. Thus, the pain experience needs to be examined with the goal of developing biobehavioral interventions (Mind/Body/Brain) to manage or prevent pain. Research is especially needed that will integrate psychological, neurochemical, and molecular approaches to the treatment of pain and that will explore basic neurobiological mechanisms of the conscious perception of pain and the affective responses to pain. (2) Psychoneuroimmunology: Research is encouraged on psycho-neuro-immune interactions, in order to characterize effects of psychological states such as stress and coping, sleep, intellectual activity, and meditation on neural and immune functions. (3) Motivation and Attitude in Movement Disorders: The extent of disability in some movement disorder patients is influenced by their motivational state. Research is encouraged on the parameters of such functional effects and on the mechanisms underlying them. (4) Emotion and Mood in Neurological Disorders: Research is needed on emotional changes that follow acute neurological insults such as stroke or trauma as well as those that accompany chronic neurodegenerative conditions and permanent or semi-permanent neural disability such as spinal cord paralysis and on the brain mechanisms underlying the interaction of mood and treatment efficacy.

(3) Types of Research

Applications must address two or more Areas of Emphasis discussed under PURPOSE and BACKGROUND. Similarly, applications should be responsive to one or more of the topics suggested by the Institutes as described in the BACKGROUND section. Applications relevant to the interests of more than one Institute are encouraged, but not required. That is, while applications may be solely relevant to the interests of a single IC, cross-cutting applications are also acceptable and encouraged.

The principal aim in this research initiative is to expand the science base in the Mind/Body field. As such, the initiative hopes to stimulate and support basic research in order to more fully understand Mind/Body relationships. In addition, assessments of the effectiveness of Mind/Body interventions, including processes underlying effectiveness, are encouraged. While this research initiative is not principally concerned with the dissemination and implementation of Mind/Body research findings, it encourages translational research that explores the best methods and cost/benefits for disseminating successful practices to individuals and health care practitioners. The state of knowledge in a given research area will determine whether implementation and dissemination components are appropriate.

Mind/Body Research is inherently interdisciplinary, and Mind/Body Centers should serve to facilitate and stimulate interdisciplinary projects. In that spirit, a variety of quantitative, qualitative, experimental, interview, and observational research methods are appropriate. Research projects or resources involving animal models or drugs may be included if they assist in explicating the relationship between cognition and health and if they do not dominate the research projects. For example, animal models or drugs may be appropriate for investigating a mediating step between mental factors and health. A related issue concerns research on the bidirectional relationships between "mind" and "body." These relationships most likely involve complex feedback loops among mental states and processes (e.g., cognition, affect), and physiological processes, which need to be taken into account. While research on the influence of biological processes on cognition and affect are appropriate subjects for this RFA, they should not be the sole or the predominant subject matter. The overall, dominant thrust of the center and its research should be on the influence of cognition (e.g., attitudes, beliefs, values) and affect on health and functioning.

SPECIAL REQUIREMENTS

(a) GENERAL

The Specialized Center Grant for this RFA minimally consists of (1) an Administrative and Planning Core, which will provide coordination, research planning, logistical, and technical

support and (2) a Research Component providing for the implementation of R01-like research projects. Optionally, the Center Grant may include (3) one or more Resource Cores (e.g., clinical populations, epidemiologic or survey research samples; statistical and methodological assistance, animal colonies) and/or (4) a Pilot Research Component providing for the implementation of pilot, feasibility, or preliminary research projects.

A Mind/Body Center should be an identifiable organizational unit formed by a single institution or a consortium of cooperating institutions. Such a center will involve the interaction of broad and diverse organizations or units. Therefore, lines of authority by the appropriate institutional officials must be clearly specified.

Interactions among the Mind/Body Research Centers are an important part of this initiative. This may be in the form of research collaborations, exchange of scientists on a visiting basis, exchange of resources and materials, and other innovative mechanisms. A requirement for all Mind/Body Research Center Principal Investigators and selected project investigators is participation in one meeting per year in the Washington, DC metropolitan area or other mutually convenient location. Funds should be included in the proposed budgets to support attendance at this annual meeting. The purpose of the meeting is to share scientific information, assess scientific progress, solve problems, identify new research opportunities, and establish priorities that will accelerate the translation of basic research findings to applied settings in patients and populations.

(b) CAREER DEVELOPMENT (REQUIRED)

The Mind/Body Centers should demonstrate a strong commitment to career development, with a plan included as part of the application. This may include new investigators or established investigators who wish to change research directions. Recruitment must include qualified women and minorities. To this end, each applicant should propose a clear policy and plan for recruitment of career development candidates. The application should state the number of career development positions proposed, the criteria for eligibility and for selection of candidates, and describe the selection process. The candidates may be advanced graduate students, post-doctoral researchers, or junior faculty. Also, the application should indicate potential mentors who are already in place at the proposed Center, briefly describe their research programs, and describe complementary activities that contribute to the interdisciplinary environment for career development (e.g., existing training grants, other career development mechanisms and relevant programs). Mentoring to enhance junior researchers' or other researchers' skills should be conducted in the context of the research, but funds may not be used for training stipends or

training not required to conduct the research. Researchers receiving mentoring may be paid a salary so long as it is received in conjunction with conducting the research.

(c) CORES

(1) ADMINISTRATIVE AND PLANNING CORE (REQUIRED)
This core manages the overall activities of the center and should include a specified director and a discrete administrative structure. Each applicant institution should name a CENTER DIRECTOR who will be the key figure in the scientific administration and management of the Center Grant. The Director should be an experienced researcher with demonstrated leadership appropriate to the coordination of the center. A minimum of 25% (minimum 10% administrative and minimum 15% research) effort on activities directly supported by the center's funding is required of the Director. The Director is encouraged, but not required, to serve as a Project Director of one of the required Research Projects (see below).

The center's Administrative and Planning Core should accomplish the following:

o Coordinate and integrate the center's activities.

o Plan and review the utilization of funds, including funds for research studies.

o Advise the Center Director on the activities of the center.

While the final administrative structure of the center will be left up to the discretion of the applicant institution, experience demonstrates that effective development of center programs requires interaction among the Director, the principal investigators of the associated research studies, appropriate institutional administrative personnel, and the staff of the NIH. Like other interdisciplinary grant programs, the success of the center depends on the involvement of scientific and professional personnel representing a variety of disciplines who must be willing to collaborate and cooperate with each other in order to facilitate the development of new knowledge. Moreover, it is important that a person with institutional management expertise and experience be involved directly with the fiscal aspects of the application and grant.

An ADVISORY COMMITTEE should be established to assist the Director in making scientific and administrative decisions related to the center. With the Director, the Advisory Committee will be responsible for the allocation of center funds as well as the identification and selection of

personnel. It will have the responsibility of evaluating and selecting the research studies proposed in the initial application and to be modified or developed during the subsequent years.
It should also review and appraise the progress of active research projects comprising the Research Component. It may perform other duties deemed appropriate by the applicant institution such as decisions concerning the career development program, the (optional) resource core(s), and the (optional) pilot research program. The committee should be composed of scientists and administrators with expertise and experience relevant to the center's scientific program. Members may be employees of the grantee institution or other institutions. However, at least one member must be from outside the center (i.e., either at the applicant institution or another institution, but not receiving support from the center).

(2) RESOURCE CORE (OPTIONAL)
The Center may establish one or more Resource Cores to provide and administer shared resources, such as data sets or populations, community or clinical research facilities, or provide research design, data collection, data analysis, or statistical services (e.g., statistics or survey cores).

(d) RESEARCH COMPONENTS

The Research Components consist of research studies funded through the Mind/Body Center. While an application need not address all three Areas of Emphasis described in the BACKGROUND section, it should include studies relevant to two of them. Similarly, the application need not address all the topical areas identified by the participating ICs. At least one of these topics should be addressed, however. Applicants are encouraged, but not required, to develop research programs cutting across traditional IC-specific mandates (e.g., cancer and heart disease) and including diverse racial/ethnic populations.

(1) RESEARCH PROJECTS (REQUIRED)
Applications must propose at least three (3) research projects to be supported during each of the requested years for grant support. Research projects may be phased in and out over the life of the Center grant. The research projects should be of scope similar to the traditional NIH research grant (R01). Ideally, these should include research, from basic to applied, oriented toward critically needed areas, and should stimulate and sustain novel collaborations and test novel ideas. The projects should evidence an interdisciplinary focus. Thus, an explanation of how the projects fit together across disciplines to promote synergy and syntheses should be included.

(2) PILOT RESEARCH PROJECTS (OPTIONAL)

Applicants may propose support for Pilot Research Projects that will facilitate the development of preliminary data sufficient to provide the basis for applications for independent research through conventional granting mechanisms (e.g., R01, P01) or improve the prospects for the Research Projects described above. Pilot Projects should take maximum advantage of the new research opportunities created through the Center. The application should provide a description of the initial pilot research grants selected for implementation during the first year of funding. The Center Grant application should also include an institutional review process, which might involve the Advisory Committee, for selecting pilot projects during the subsequent years of the grant. Pilot Research studies are typically limited to a period of one to two years. No more than $100,000 (direct costs) per year may be devoted to Pilot Research Projects. (This is not a per project maximum, but rather an aggregated maximum of all Pilot Research Projects.)

(e) CONSORTIUM ARRANGEMENTS (OPTIONAL)

See SUPPLEMENTAL INSTRUCTIONS FOR COMPLETING PHS FOR 398. These instructions can be obtained at http://www1.od.nih.gov/obssr/mbpage.htm or from the program staff listed under INQUIRIES.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons to exclude them.(See NIH Guide to Grants and Contracts, March 6, 1998 or http://www.nih.gov/grants/guide/notice-files/not98-024.html.)

LETTER OF INTENT

Prospective applicants are asked to submit, by March 1, 1999, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel (including research project collaborators and consultants) and participating institutions, and the number and title of this RFA. Although a letter of intent is not binding and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and avoid conflict of interest in the review.

The letter of intent is to be sent to:

Ronald P. Abeles, Ph.D.
Office of Behavioral and Social Sciences Research
National Institutes of Health
7201 Wisconsin Avenue, Room 2C234, MSC 9205
Bethesda, MD 20892-9205
Telephone: (301) 594-5943
FAX: (301) 402-0051
Email: Ronald_Abeles@nih.gov

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants. Applications kits are available at most institutional offices of sponsored research and from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone (301) 435-0714, Email: GrantsInfo@nih.gov. Applications are also available on the World Wide Web at http://www.nih.gov/grants/forms.htm.

In addition, applicants should obtain and follow guidelines specified in SUPPLEMENTAL INSTRUCTIONS FOR COMPLETING PHS FORM 398. These instructions can be obtained from http://www1.od.nih.gov/obssr/mbpage.htm or from the program staff listed under INQUIRIES.

The RFA label available in the PHS 398 (rev. 4/98) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title, and number, must be typed on Line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, original of the application, including the Checklist, and four signed photocopies of the application in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, send one additional copies of the application to:

Ronald P. Abeles, Ph.D.
Office of Behavioral and Social Sciences Research
National Institutes of Health
7201 Wisconsin Avenue, Room 2C234, MSC 9205
Bethesda, MD 20892-9205

It is important to send these copies at the same time that the original and four copies are sent to the Center for Scientific Review (CSR).

Applications must be received by April 23, 1999. If an application is received after that date, it will be returned to the applicant without review. The CSR will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by CSR and responsiveness by the participating NIH entities. Incomplete and nonresponsive applications will be returned to the applicant without further consideration. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the CSR in accordance with the review criteria stated below. As part of the initial merit review, all applications will receive a written critique and may undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

Review Criteria

In addition to the criteria list below, the initial review group will examine: the appropriateness of proposed project budget and duration; the adequacy of plans to include both genders, minorities (and their subgroups), and children as appropriate for the scientific goals of the research, and plans for the recruitment and retention of subjects; the provisions for the protection of human and animal subjects; and the safety of the research environment. Review criteria for the components of the center are:

A. Center as a Whole

o Quality of integration of center components to an over-arching theme that integrates and focuses the center, as well as the presence of an essential relationship of each component to the theme. Interdependency and linkages of components to each other need to be demonstrated for at least a significant nucleus of components.

o Evidence of synergy as components are configured in the applications. To aid in these determinations, reviewers may look at the quality of provisions for the sharing of resources, procedures for formal and informal planning, and plans for developmental or pilot work in order to determine if the application reflects a depth and breadth of expertise and experience not normally present in an individual research project grant.

o The involvement of different scientific disciplines or subdisciplines in the center's activities and the demonstration of substantial interaction among scientists from different disciplines or subdisciplines and different perspectives.

B. Administrative and Planning Core

o Organizational and administrative structure and support conducive to research, synergy, and joint planning. Plans for development and maintenance of an environment that promotes the conduct of the highest quality of research, innovation, and leadership. Demonstrations of past productivity may be used as evidence of likely future productivity.

o Advisory structures that provide appropriate and objective advice and evaluation, as needed. An internal process that allows for priority setting and decision making to sustain the center. Appropriate specification of criteria and processes for determining and sustaining individual participation in the center based on productivity, research direction, and overall contribution. Structure for long range planning and evaluation of center activities.

o Adequacy of provisions for sharing of data base development and analytic capacities. Quality and extent of data analytic capacities, data base facilities, and data resources.

o Appropriateness and adequacy of facilities for administrative, research, and shared resources, including a clearly identifiable physical location for the center that assures necessary functions can occur. Programmatic structure that effectively promotes productive scientific interactions and takes maximum advantage of the applicant institution's Mind/Body Research capacity.

o Facilities that indicate the center is or would soon be a national scientific research resource. Clear and convincing evidence of the applicant institution's substantial commitment to the center and appreciation of its goals.

o Evidence that core components contribute toward cost-effectiveness and quality control in resource utilization. Arrangements for internal quality control of research, publications, and grant applications.

C. Research Cores

o SIGNIFICANCE: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field? For Pilot Research Projects, what is the likelihood that the research will contribute to the development of interdisciplinary programs or more mature research endeavors?

o APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

o INNOVATION: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

o INVESTIGATORS: Is each investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

o ENVIRONMENT: Does the scientific environment in which the work will be done contribute to the probability of success of the project? Do the proposed studies take advantage of unique features of the scientific environment or employ useful collaborative arrangements?

D. Qualifications of Key Staff

CENTER DIRECTOR
o Ability to lead a scientific and career development program, as noted by scientific achievements, productivity, stature in a relevant field, and planned activities.

o Ability to lead administrative and operational aspects of the center, as noted by administrative skills, achievements, and planned activities.

o Ability to develop a role for the center as a national resource.

o Adequacy of commitment of time and effort for the research and administration of the center. (A minimum of 25% effort on activities directly supported by the center's funding is required.)

COLLABORATING INVESTIGATORS
o Quality of cadre of investigators and their productivity, as noted by their scientific achievements, honors, and recognition.

o Quality of interactions among investigators and investigative teams.

o Breadth of expertise represented among investigators.

o Quality of investigators at collaborating sites and the nature of collaborations.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications submitted in response to this RFA. The following will be considered in making funding decisions:

o The quality of the proposed project as determined by peer review
o Availability of funds
o The research priorities of the participating NIH Institutes/Centers.

INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Applicants may also subscribe to the OBSSR's automated e-mail service in order to obtain subsequent information about this RFA and the Mind/Body Centers Program. To subscribe, please send a message addressed to listserv@list.nih.gov. The message should read SUBscribe Mind-Body-L [your full name]. The message is case sensitive; so capitalize as indicated! Do not include the brackets. For example, for Robin Smith to subscribe, the message would read "SUBscribe Mind-Body-L Robin Smith" (omit the quotation marks). The subject line should be blank. Subscribers will receive a confirmation of their subscription along with instructions on how to use the LISTSERV and how to unsubscribe.

Direct general inquiries to:

Dr. Ronald P. Abeles
Office of Behavioral and Social Sciences Research
National Institutes of Health
7201 Wisconsin Avenue, Room 2C234, MSC 9205
Bethesda, MD 20892-9205
Telephone: (301) 594-5943
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Direct inquiries regarding specific programmatic issues to the staff of the appropriate Institute/Center:

National Cancer Institute
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Direct inquiries regarding fiscal matters to the staff of the appropriate Institute/Center:

National Cancer Institute
Mr. William Wells
Grants Management Branch

Executive Plaza South, Room 243
Bethesda, MD 20891-7150
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National Heart, Lung, and Blood Institute
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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos.93.395 and 93.393 (NCI), 93.937 (NHLBI), 93.866 (NIA), 93.891 (NIAAA), 93.846 (NIAMS), 93.929 (NICHD), 93.121 (NIDCR), 93.279 (NIDA), 93.859 (NIGMS), 93.242 (NIMH), 93.853 (NINDS), and 93.361 (NINR). Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410), as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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